

### REMARKS

Claims 1–21 are pending in the application, but claims 14–21 have been withdrawn from consideration as being drawn to a non-elected invention. Accordingly, claims 1–13 remain under consideration.

Claims 1–13 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2002/01245266.

Claims 1–13 also stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,692,361 issued to Johnston et al. ("Johnston") in view of one or more of the following references: U.S. Patent No. 6,326,010 issued to Sano et al. ("Sano"); U.S. Patent No. 4,910,147 issued to Bacehowski et al. ("Bacehowski"); and U.S. Patent No. 4,936,456 issued to Bell et al. ("Bell"). Applicants respectfully traverse these rejections.

#### Rejection of Claims 1–13 under 35 U.S.C. § 102(e)

Claims 1–13 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2002/01245266 ("Lewis").

Applicants have submitted herewith a Declaration Under 37 C.F.R. § 1.132 to remove the Lewis publication as a reference. Applicants' declaration establishes that the subject matter disclosed in U.S. Patent Application No. 09/804,047 (published as the Lewis publication) was invented by the same inventive entity as the subject matter claimed in the present application.<sup>1</sup> Accordingly, the Lewis publication is not prior art against the present application under 35 U.S.C. § 102(e) because the Lewis publication is not "an application for patent ... by another" as § 102(e) expressly requires. Consequently, Applicants respectfully request that the Examiner reconsider and withdraw the present § 102(e) rejections.

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<sup>1</sup> The declaration further establishes that it was not discovered that two inventors (Messrs. Habison and Eder) had been erroneously omitted from the application until February 2003, five months after the '047 application and its PCT counterpart (PCT/US02/07581) had already been published naming the erroneous inventive entity. Although by that time the '047 application had been abandoned, making it impossible to correct inventorship therein, Applicants did correct the inventorship in the PCT application.

Rejection of Claims 1–6 and 8–26 under 35 U.S.C. § 103(a)

Claims 1–7 and 1–13 rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Johnston in view of Sano. Applicants respectfully traverse this rejection.

The Examiner alleges that Johnston generally discloses that containers defined by thermally sealed walls are used to package parenteral products including plasma, intravenous solutions, nutrition products, and dialysis solutions. The Examiner further alleges that Sano discloses that it is desirable to store albumin in a sterilized plastic vessel, and that albumin is found in blood plasma. The Examiner has therefore concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to store albumin in flexible bags of Johnston based on the teachings of Sano. Applicants respectfully traverse this rejection.

As shown below in more detail, the Examiner's rejections are improper. The Examiner has not only failed to show any teaching, motivation or suggestion to combine the cited references, but has also ignored clear statements in Sano teaching away from the present invention. Moreover, the cited references, taken together or separately, do not disclose or suggest all of the limitations of the claims. For both of these reasons, the Examiner has failed to satisfy her burden of presenting a *prima facie* case of obviousness. In re Reuter, 210 USPQ2d 249 (CCPA 1981)

As the Examiner is aware, three criteria must be met to establish a *prima facie* case of obviousness: first, there must be some suggestion, incentive or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and third, the prior art references must teach or suggest all the claim limitations. See In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1988). Obviousness cannot be established by combining the teachings of a reference to produce the claimed invention, absent some teaching or suggestion supporting the combination of the references. ACS v. Montefiore Hospital Systems, Inc., 221 USPQ 929, 933 (Fed. Cir. 1984). Furthermore, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the Applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Here, the invention of Johnston “relates to a film laminate structure for flexible containers.” (Johnston, col. 1, ll. 6–7.) According to Johnston, “flexible containers are utilized in the medical industry for containing, *inter alia*, parenteral solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma.” (Johnston, col. 1, ll. 11–14.)

In contrast, the disclosure of Sano relates specifically to replacing conventional glass containers that are used to store albumin with a rigid molded “plastic vessel containing an albumin.” (Sano, col. 1, ll. 9–10.) Because Johnston relates to flexible film laminate containers, while Sano relates to rigid plastic molded containers, there is absolutely no teaching or suggestion supporting the combination of these references. Johnston’s statement that flexible containers are used for containing plasma, read in conjunction with Sano’s statement that albumin is “a protein mostly included in blood plasma” (col. 1, l. 17), would not lead one skilled in the art to combine the teachings of Johnson and Sano because they relate to entirely different types of containers (i.e. flexible film container versus molded rigid bottle). Accordingly, there is no teaching or suggestion in the references (other than in the Applicants’ application) to make this combination. Thus, Applicants respectfully submit that the Examiner has used improper hindsight (i.e., used the teachings of Applicants’ invention as a template) to obtain the combination. Moreover, since there is no teaching or suggestion to combine the disclosures of Johnson and Sano, the Examiner has failed to present a *prima facie* case of obviousness. For this reason Applicants respectfully submit that this obviousness rejection is improper and should be withdrawn.

Moreover, even if the two cited references were properly combinable, they would not render Applicants’ claimed invention obvious over the prior art because the combination would not result in the invention identified in Applicants’ claims. For example, while Johnston states that various solutions, including plasma, may be contained in flexible containers, there is absolutely no disclosure, teaching or suggestion in Johnston indicating that flexible polymeric containers are suitable for filling with and storing *albumin*. The same is true of Sano – that reference does not state that albumin can be packaged and stored in *flexible* polymeric containers. For this reason alone Applicants’ claims are patentable over these references, either alone or in combination.

Indeed, Sano itself shows that albumin has not been packaged even in rigid plastic containers, let alone flexible polymeric containers. Sano has a priority date significantly later than Johnston (1999 versus 1984), and Sano teaches that in 1999, over 15 years after the disclosure of Johnston, albumin was still being packaged in glass vessels because it had not yet been discovered how to package albumin in a plastic container:

the substitutions of glass vessels with plastic vessels has been attempted, but plastic vessels containing an albumin preparation having sufficient functions have not been obtained because of thermal denaturing of the albumin by the heat of hermetical sealing. (Sano, col. 2, ll. 5–10.)

As a proposed replacement for glass bottles, Sano discloses a *rigid*, blow-molded, plastic container. Particularly, Sano's container is described as follows:

According to the method for producing an albumin preparation vessel of the present invention, a plastic molded material is extruded in a cylindrical form in a molten state into a pair of divided body dies and one end of the plastic molded member in the cylindrical shape is closed in the body dies. A main body portion is molded by means of blowing compressed gas into an inner portion of the molded member, or bringing the inner portions of the body dies into a vacuum state while the molded member still remains in the body dies.

....

The albumin preparation vessel of the present invention is a cylindrical vessel made of the above plastic having a head portion formed by thermally sealing an open end which is disposed in the upper position. A horizontal section of the vessel main body or the opening portion thereof is preferably circular, elliptical, or approximately quadrangular. The vessel has an oblique portion by which the contents are easily drained towards the head portion and which is disposed in the upper position of the cylindrical vessel, and which is called a shoulder portion, and a neck portion thereon. (Sano, col. 4, ll. 16–25, 36–46.)

The cited references demonstrate that at the time of Johnston albumin was not packaged in flexible polymeric containers. Similarly, even at the time of Sano (15 years after Johnston) albumin still was not packaged in *flexible* polymeric containers. While Sano teaches that rigid molded plastic containers could be used to replace the traditional glass bottle vessels, even Sano does not teach that albumin could be packaged in a flexible polymeric container. Thus, even if the two references were properly combinable they would not result in Applicants' claimed invention.

Moreover, the Examiner cannot equate albumin to other parenteral solutions, including plasma, for packaging purposes merely because albumin is found in plasma. For example, just as plasma is not the equivalent of red blood cells, plasma is not the equivalent of albumin. Rather, in the body plasma is merely a carrier for albumin. Thus, the Examiner's assertion that the solutions identified in Johnston are equivalent to albumin for packaging purposes is erroneous.

Unlike other parenteral solutions, albumin presents unique problems when attempting to fill, seal, and store in a flexible container. As shown above, Sano specifically teaches the problems associated with packaging albumin, even in a rigid molded container, and explains that because of such packaging and sterilization problems, it had previously been impossible to package albumin in a rigid plastic container; but even Sano does not propose a flexible polymeric container. As the Background section of Applicants' patent application explains, "albumin is a sulfur-containing, water-soluble protein that *congeals when heated*, and occurs in blood." Further, Applicants have explained that while various pharmaceuticals are packaged in polymeric bags and sterilized in a post-packaging autoclaving step (such as is identified in the teachings of Johnston), until Applicants' invention such a process was not possible with albumin. Specifically, the heat required to kill bacteria in the autoclaving process will congeal the albumin, thereby rendering it useless. Additionally, conventional form-fill-seal packaging machinery introduces heat to certain areas of the polymeric packaging material to create the seals. If the heat contacts the albumin during the sealing process, the albumin may congeal or otherwise denature just as it would during high-temperature sterilization. Sano itself points this out:

[P]lastic vessels containing an albumin preparation having sufficient functions have not been obtained because of *thermal denaturing of the albumin by the heat of hermetical sealing*. (Sano, col. 2, ll. 5-10.)

For these reasons, albumin has not previously been packaged in a flexible polymeric material. Neither Johnston nor Sano provides any solutions to these problems so as to allow one to package albumin in a flexible polymeric container. Indeed, Sano's stated concerns regarding the detrimental effect of heat sealing would discourage one of ordinary skill from attempting to package albumin in a flexible container. Sano thus teaches away from the claimed invention.

Other than Applicants' own products produced in accordance with the present invention, Applicants are not aware of any use of a flexible container for filling therein and storing albumin. Accordingly, even though Johnston has identified various solutions as being capable of being stored in flexible containers, one of ordinary skill in the art would not have understood that albumin could be so stored. Rather, one of ordinary skill in the art would readily understand that albumin was incapable of being packaged and stored in a flexible container until Applicants developed their manufacturing process. The disclosure of Sano, which is dated 15 years after Johnston but still says nothing to suggest that albumin may be packaged in flexible containers, bears this out. Thus, even if Sano were properly combinable with Johnston, the combination of these references would not disclose or render obvious Applicants' claimed invention. For this reason Applicants respectfully submit that claims 1-7 and 11-13 are patentable as originally presented.

Applicants also respectfully submit that dependent claims 8-10, rejected under other grounds and with additional references, are similarly patentable as presented. If an independent claim is nonobvious under § 103, then any claim depending therefrom is also nonobvious. In re Fine, 837 F.2d 1071 (Fed. Cir. 1988). Claims 8-10 depend from claims 1 and 3, which are patentable as submitted for the reasons explained above. Consequently, Applicants respectfully submit that rejected claims 8-10 are patentable for at least the same reasons as claims 1 and 3.

In view of the foregoing remarks, Applicants respectfully submit that this application is in condition for allowance and respectfully request such action in the next communication from the Office. Applicants invite the Examiner to contact the undersigned representative to discuss any further issues or questions concerning this application.

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Respectfully submitted,

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